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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/690,451

10/21/2003

Michael C. Sherman

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30565

7590

04/08/2008

WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP  
111 MONUMENT CIRCLE, SUITE 3700  
INDIANAPOLIS, IN 46204-5137

EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

04/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/690,451	<b>Applicant(s)</b> SHERMAN ET AL.	
	<b>Examiner</b> JAMES L. SWIGER	<b>Art Unit</b> 3733	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/29/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 10-16 and 38-39, and 63-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Casey et al. (US Patent 4,781,183). Casey et al. disclose a surgical orthopedic device that is used to secure two bone portions comprising an elongate member (See Fig. 4) that is capable of allowing both translational or rotational movement when attached to and allowing bone to heal (see Fig. 7), at least one bone fastener (5), and also teaches the use of a reinforcing component (see Col. 3, lines 65-68 through Col. 4, lines 1-10). The biodegradable reinforcing component loses stiffness and strength over time gradually translating the reinforcement back to the bone for proper healing. The device is made of a biocompatible material and has associated properties of elasticity for the healing of the bone. The reinforcing component may also be made of polymer materials (see Col. 4, lines 31-40). The elongate member may also be considered a plate (1) and has a plurality of voids (2/3). In that regard, the plate may be considered imperforate. As taught in the reference the elongate member/plate may have a reinforcing component that may be placed in the plurality of voids. The plate may have different materials with different ingredients. And the surface of the plate is curved, thus having different surfaces.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casey et al. '183 in view of Cohen (US Patent 6,206,882). Casey et al. discloses the claimed orthopedic device except for a device having two portions that have different cross sectional areas. Cohen discloses an elongate device that is considered to have different cross sectional areas at different locations (taken from different locations such as from slot 16 versus section 12 from figure. 1), and wherein different cross sections provide a degree of deformation for use in spinal fixation (Col. 2, lines 20-23). These portions are adjacent. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Casey et al. having first and second portions and a portion to permit deformation in view of Cohen to better use and provide appropriate orthopedic fixation to the surgical area during use.

Claims 24-35, 47-52 and 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casey et al. '183 in view of Severns et al. (US Publication 2002/0173792). Casey et al. discloses the claimed orthopedic elongate device except for more specifically an orthopedic rod. Severns et al. discloses an orthopedic rod (see Fig. 1) that provides bone support, is capable of providing spinal fixation if appropriately

anchored, has a plurality of voids (40 and 50), and has reinforcing material disclosed as degradable spacers (46) that slowly transfer force back to the bone for healing. The device is also disclosed as having a cannulated shaft (34) in which some of the reinforcing component may reside as it decays (see view in Fig. 3). The device also discloses two different portions of different cross sectional diameters (opposing ends), and that the rod may bend to fit its appropriate area (par 0048). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Casey et al. having at least the above modifications in view of Severns et al. '792 to better use the device and provide appropriate, timed transfer of support to the bone structures as required.

Claims 7-10, 22-23, 36-37, and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casey et al. 183 and also in view of Cohen and Severns, et al. respectively. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the reinforcing material degrade at the disclosed rate since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (with regard even to orthopedic healing rates) involves only routine skill in the art. In re Aller, 105 USPQ 233.

### ***Response to Arguments***

Applicant's arguments submitted 1/9/2008 have been considered but are not persuasive. It is understood that Casey et al. teaches a plate made of various materials. However, it is noted that Casey et al. still teaches the claimed apparatus including an

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elongate member (plate body), a reinforcing component, and a bone fastener. The reference specifically states that the plate may be made of multiple materials and further goes on to state that "the invention uses a combination of materials which may consist of a bioabsorbable polymer and a reinforcing fiber (which may or may or may not be bioabsorbable)." One is not necessarily an ingredient of another. These fibers are combined in such a way as to vary or transfer stiffness as the bone heals.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/  
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733

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